

IN THE CLAIMS

Please substitute pending claims 1, 7 and 23 with amended claims 1, 7 and 23, as shown below:

E1  
Sub F1

1. A stable, aerosolizable composition, the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of about 10-70 parts of ethanol, about 10-30 parts of water and greater than about 30-80 parts of propylene glycol having a combined total of 100, provided that:

- (i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10  $\mu$ M;
- (ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream; and
- (iii) the composition is pharmaceutically suitable for rapid bronchial delivery to the lung of a subject.

E2  
Sub F1 Cont

7. A composition as defined in Claim 1 wherein the volumetric ratios of ethanol : water : propylene glycol are selected from those in the range of from about 10 – 70 : about 10 : greater than about 30 – 80, respectively, having a combined total of 100.

E3  
Sub F1 Cont

23. A stable, aerosolizable composition, the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of about 10-70 parts of ethanol,

83  
Sub F  
Cont

about 10-30 parts of water and greater than about 30-80 parts of a glycol selected from the group consisting of polypropylene glycol and polyethylene glycol having a combined total of 100, provided that:

- (i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10  $\mu$ M; and
- (ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream; and
- (iii) the composition is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject.

#### REMARKS

Claims 1-4, 7-12 and 14-23 are currently pending. Claims 1, 7 and 23 have been amended to place the claims in better condition for allowance or appeal. Accordingly, Applicant respectfully submits that no new matter has been added by way of this amendment.

In the Office Action dated January 29, 2003, the Office rejected claims 1-4, 7-12 and 14-23 under 35 U.S.C. § 103(a) as unpatentable over Touitou (5,716,638) in view of Patel et al. (6,294,192) in further view of LaMastro et al. (5,258,336). Reconsideration of these rejections is hereby requested.

#### *I. Rejections under 35 U.S.C. § 103(a)*

Claims 1-4, 7-12 and 14-23 were rejected under 35 U.S.C. § 103(a) as unpatentable over Touitou (5,716,638) in view of Patel et al. (6,294,192) in further view of LaMastro et al. (5,258,336). These rejections are traversed for the reasons set forth below. Claims 1, 7 and 23 have been amended to point out more particularly and claim more distinctly the subject matter of the claimed invention and to place the claims in better condition for appeal.